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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,878	01/23/2002	Macino Giuseppe	6360	5622
7590	01/25/2005		EXAMINER	
Arlene J Powers 225 Franklin Street Suite 3300 Boston, MA 02110			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 01/25/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/913,878	Applicant(s) GIUSEPPE ET AL.	
	Examiner Celine X Qian Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) 12, 13 and 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
6) <input type="checkbox"/> Other: _____. |
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Art Unit: 1636

DETAILED ACTION

Claims 1-23 are pending in the application. Claims 12, 13, 15-22 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-11, 14 and 23 are currently under examination.

This Office Action is in response to the Amendment filed on 11/8/04.

Response to Amendment

Acknowledgment is made of Applicant's amendment of the specification, and the application now satisfies the sequence compliance rules.

The rejection of claims 1-11, 14 and 23 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1-5, 7-11, 14 and 23 under 35 U.S.C. 112 1st (written description and enablement) paragraph is maintained for reasons set forth of the record mailed on 5/5/04 and further discussed below.

The rejection of claim 23 under 35 U.S.C. 101 is maintained for reasons given below.

Claims 7-11 and 14 are objected to for reasons given below.

The objection to the specification is maintained for reasons given below.

Claim 6 is rejected under 35 U.S.C. 112 2nd paragraph for reasons given below.

Applicants are reminded that claims 12, 13, 15-22 are withdrawn from consideration for being directed to non-elected subject matter. The status of these claims in the Amendment should be amended as "withdrawn" to reflect the actual status of these claims.

Response to Arguments

Claim Rejections - 35 USC § 112

In response to the written description rejection, Applicants argue that Figure 5 discloses 4 other sequences that share homologies with a sequence of qde-1 protein, in particular that the homology between tomato RNA-dependent RNA polymerase RdRP and qde-1 is limited to the aa. region 710-1282 of SEQ ID NO:2. Applicants further argue that the claimed species have also been described by other identifying characteristics such as the RNA-dependent RNA polymerase activity. Applicants argue that it is not necessary for the specification to teach what domain is necessary and sufficient for the silencing activity because it is not the claimed subject matter. Applicants assert the claimed subject matter is a protein having a silencing activity and a RNA-dependent RNA polymerase domain, not a domain having both silencing and RNA-dependent RNA polymerase activity. Applicants further provided 4 references published after the filing of the instant specification (Dalmay et al., Catalonotto et al., Makeyev et al., and Forrest et al.) to demonstrate the silencing activity of the claimed proteins. Applicants thus conclude that the written description requirement is met.

These arguments have been fully considered but deemed unpersuasive. The reasons for this rejection were discussed in detail in the office action mailed on 5/5/04. As discussed in the previous office action, the claimed genus of nucleic acid sequences encompasses potentially a large genus of polynucleotides that have a silencing activity and comprises a RNA-dependent RNA polymerase domain having 30%-100% homology with SEQ ID NO:2 or functional portions. The specification only describes one qde-1 gene that has both characteristics. Although four sequences disclosed in Figure 5 share sequence homology with SEQ ID NO:2,

Art Unit: 1636

they are not proteins having silencing activity and comprising the RdRP domain. The specification only described the complete structure of one specie out of a broad genus of claimed polynucleotides. As such, the complete structure of the entire claimed genus is not describe by the instant specification. In response to Applicants' argument regard to other identifying characteristics, Applicants are reminded that the "other identifying characteristics" of the written description requirement refers to the characteristics that relate to the functionality of the claimed protein. Since the specification does not teach what is the structure of the protein that is necessary and sufficient for the silencing activity, functional portions of the claimed protein cannot be determined. In addition, whether proteins share certain homology with SEQ ID NO:2 would have the silencing activity cannot be determined either. As such, the specification fails to provide sufficient description of the complete structure of the claimed genus or other identifying characteristics shared by the claimed genus necessary for their function. Furthermore, the written description requirement must be satisfied at the time of filing and cannot be remedied by post filing art. Therefore, this rejection is maintained.

With regard to claim 23, although it is rejected under 101, for the purpose of compact prosecution, this claim is interpreted to the best of examiner's knowledge. As such, the written description rejection applies to claim 23 since it is interpreted as a product.

In response to the enablement rejection, Applicants argue that the teaching of specification is not limited since Figure 5 discloses other members of the family sharing claimed homologies. Moreover, Applicants argue that tomato RdRP has a silencing activity in plants based on the teaching of Dalmay et al., a post filing reference. Applicants also indicated all the

Art Unit: 1636

post filing art presented demonstrate a relationship in which protein comprising a RdRP domain and having silencing activity.

Applicants' argument has been fully considered but deemed unpersuasive. The reasons for the non-enablement of the claimed invention were discussed in detail in the office action mailed on 5/5/04. The teaching of the specification is limited with respect to the broad scope of the claim. The sequences disclosed in Figure 5 shares homology with qde-1, however, the specification does not teach whether they have the function of silencing activity. The post filing evidence provided in Dalmay et al. would only provide support for the enablement of the SDE1, a plant homologue of qde-1, for having silencing activity in plants, and the rest of the references demonstrate the silencing activity of the qde-1. As such, for the claims that encompasses protein having silencing activity and having 30%-100% homology with only a portion of SEQ ID NO:2, it is unclear whether they would have the claimed silencing activity. Contrary to Applicants' assertion, the discussion of unpredictability of the function of a protein based on sequence homology is pertinent to the claimed invention because it indicates a general problem in the art. As such, the claimed invention is only enabled to encompass qde-1 and SDE1. Therefore, this rejection is maintained.

Claim Rejections - 35 USC § 101

In response to the 101/112 2nd rejection of claim 23, Applicants amended claim to recite a method step. However, such amendment does not overcome the 101 rejection of the record. According to the 101 statute, the claimed subject matter is limited to "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," which this claim belongs to none of the above. Therefore, this rejection is maintained.

Art Unit: 1636

Claim Objections

Claims 7-11 and 14 are objected to because the recitation of “expression vector,” “bacterial organism” or “fungus.” Applicants are advised to add “an” or “a” prior to the terms to indicate the singular form of the claimed invention.

Specification

The amendment to the specification to introducing subtitles for the sections is acknowledged. However, the specification still recites “not human animal,” which is in proper English format. As indicated in the previous office action, amending the term to “non human animal” would obviate this objection.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of “wherein said nucleotide sequence is the sequence of SEQ ID NO:2 or its complementary sequence” renders the claim indefinite because it is unclear what kind of sequence applicants are referring to. SEQ ID NO:2 is an amino acid sequence which cannot have a complementary sequence. The claim is drawn to an isolated nucleotide sequence. As such, the metes and bounds of the claim cannot be established.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636



DAVE TRONG NGUYEN
PRIMARY EXAMINER